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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #05-259

DIGEST

Amends 410 IAC 1-4-1.1 to amend the definition of bloodborne pathogens. Amends 410 IAC 1-4-4.3 to add a definition of HCV. Amends 410 IAC 1-4-8 to update the sterilization requirements for equipment and environmental surfaces. Effective 30 days after filing with the Secretary of State.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

The Indiana State Department of Health (ISDH) is unable to provide a precise estimate of the number of individuals affected by this rule. The ISDH estimates the current number of individuals who have professional, employment, or volunteer duties that require the individual to have direct contact with blood or other body fluids as part of their medical, public health, or public safety duties exceeds 300,000. The ISDH estimates over 20,000 facilities may be affected due to the provision of services that may include exposure to blood or other body fluids.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed amendments to the Universal Precautions Rule do not add any annual reporting, record keeping, or other administrative costs for small businesses to comply with the rule.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The proposed amendments to the Universal Precautions Rule do not increase the economic impact on small business for complying with the universal precautions rules.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

Failure to comply with universal precautions will increase the likelihood that an individual who is exposed to blood or body fluid will acquire a dangerous communicable disease.

5. Regulatory Flexibility Analysis

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The proposed amendments provide clarification to existing requirements and update requirements based on best practices. Less stringent requirements would increase the likelihood that an individual exposed to blood or body fluids would acquire a dangerous communicable disease.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The proposed amendments do not change schedules or deadlines for compliance or reporting requirements.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

There are no new reporting requirements imposed by the proposed amendments to the rule.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

Universal precautions are best practices for the prevention of the spread of dangerous communicable disease through contact with blood or body fluids.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

Exposure to dangerous communicable disease through blood or body fluids is a risk for small and large businesses.

Conclusion:

The proposed amendments provide clarification to existing requirements and update requirements based on best practices. Less stringent requirements would increase the likelihood that an individual exposed to blood or body fluids would acquire a dangerous communicable disease. The amendments do not require additional costs for small businesses.

410 IAC 1-4-1.1
410 IAC 1-4-4.3
410 IAC 1-4-8

SECTION 1. 410 IAC 1-4-1.1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-4-1.1 “Bloodborne pathogens” defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 1.1. “Bloodborne pathogens” means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, **the following:**

- (1) HBV. ~~and~~
- (2) HCV.
- (3) HIV.

(Indiana State Department of Health; 410 IAC 1-4-1.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

SECTION 2. 410 IAC 1-4-4.3 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-4-4.3 “HBV” and “HCV “ defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11

Sec. 4.3. (a) “HBV” means hepatitis B virus.

(b) “HCV” means hepatitis C virus. *(Indiana State Department of Health; 410 IAC 1-4-4.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

SECTION 3. 410 IAC 1-4-8 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-4-8 Precautions generally

Authority: IC 16-41-11-9

Affected: IC 16-19; IC 16-41-11

Sec. 8. (a) All covered individuals and health care workers under this rule shall comply with the requirements imposed under the Indiana occupational safety and health administration’s bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(b) The operator and all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility providing services to patients or other members of the public in which there is a reasonably anticipated risk of skin, eye, mucous membrane, or parenteral contact with human blood or other potentially infectious materials shall also comply with the following requirements:

(1) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(2) Heating procedures capable of sterilization must be used when heat stable, nondisposable equipment is sterilized. **Monitoring of heat labile, reusable equipment requiring sterilization must be sterilized by chemical means. Records must be maintained to document procedures shall include documentation** of the following:

(A) ~~Duration of Each sterilization technique: cycle.~~

(B) ~~Mechanisms for determination of effective sterility.~~

(B) **Use of chemical indicators when sterilizing packaged nondisposable equipment.**

(C) **That biological indicators were used within thirty (30) days before the current sterilization procedure.**

(C) ~~(D) Routine monthly equipment maintenance inspections: according to manufacturer’s recommendations.~~

~~These Documents~~ **required under this subdivision** must be made available to the department upon request.

(3) ~~Reusable equipment requiring sterilization that is destroyed or altered by heat must be sterilized by chemical means.~~

(3) ~~(4) Environmental surfaces and equipment not requiring sterilization which that have been contaminated by blood or other~~

potentially infectious materials shall be cleaned ~~then decontaminated~~ **with an absorbent material before disinfection.** Disinfectant solutions shall **be either of the following:**

(A) ~~be A hospital grade, tuberculocidal germicide registered with the Environmental Protection Agency (EPA) registered for use as a hospital disinfectant and labeled tuberculocidal or registered germicide with specific inactivation claims against HIV and HBV.~~

(B) ~~be A sodium hypochlorite five-tenths percent (0.5%) concentration, by volume (common household bleach in ten percent (10%) concentration in water); the solution shall be dated and shall not be used if it is more than after twenty-four (24) hours old as follows:~~

(i) ~~A minimum of 1:100 dilution (one-quarter (¼) cup of five and twenty-five hundredths percent (5.25%) common household bleach in one (1) gallon of water).~~

(ii) ~~A 1:10 dilution (one (1) part five and twenty-five hundredths percent (5.25%) common household bleach in ten (10) parts water) shall be used when a blood, culture, or OPIM spill occurs in the laboratory setting.~~

~~(4)~~ (5) If a patient's diagnosis, laboratory analysis, or medical condition requires additional infection control measures or isolation, those specific measures apply in addition to the requirements of this rule and other requirements found at IC 16-19.

(Indiana State Department of Health; 410 IAC 1-4-8; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on February 23, 2006 at 11:30 a.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed rule to amend the definition of bloodborne pathogens, add a definition of HCV, and update the sterilization requirements for equipment and environmental surfaces.

These rules are amended to meet the standards of the Centers for Disease Control and Prevention (CDC).

Copies of these rules are now on file at the Public Health Preparedness Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl
Deputy State Health Commissioner
Indiana State Department of Health